

WHAT WE CLAIM IS:

1. A detection probe for use determining the presence of *Trichomonas vaginalis* in a test sample, said probe being up to 100 bases in length and comprising a target binding region which forms a hybrid stable for detection with a sequence contained within a first target sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4 under stringent hybridization conditions, wherein said probe does not form a hybrid stable for detection with nucleic acid derived from *Trichomonas tenax* under said conditions.

2. The probe of claim 1, wherein said target binding region comprises an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region of said first target sequence.

3. The probe of claim 1, wherein said probe is up to 50 bases in length, and wherein said target binding region comprises an at least 15 contiguous base region which is perfectly complementary to an at least 15 contiguous base region of said first target sequence.

4. The probe of claim 1, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of said first target sequence.

5. The probe of claim 1, wherein the base sequence of said target binding region is at least 90% complementary to the base sequence of said first target sequence.

6. The probe of claim 1, wherein the base sequence of said target binding region is perfectly complementary to the base sequence of said first target sequence.

7. The probe of claim 1, wherein the base sequence of said probe consists of a base sequence which is at least about 80% complementary to the base sequence of said first target sequence.

8. The probe of claim 1, wherein the base sequence of said probe consists of a base sequence which is at least about 90% complementary to the base sequence of said first target sequence.

5 9. The probe of claim 1, wherein the base sequence of said probe consists of a base sequence which is perfectly complementary to the base sequence of said first target sequence.

10 10. The probe of claim 1, wherein the base sequence of said target binding region is perfectly complementary to all or a portion of said first target sequence, and wherein said probe does not comprise any other base sequences which stably hybridize to nucleic acid derived from *Trichomonas vaginalis* under said conditions.

15 11. The probe of claim 10, wherein said probe is a self-hybridizing probe under said conditions and in the absence of said first target sequence.

12. The probe of claim 11, wherein said probe comprises a pair of interacting labels.

20 13. The probe of claim 1, wherein said probe comprises a detectable label.

25 14. The probe of claim 1, wherein said target binding region includes at least one ribonucleotide modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety.

15. The probe of claim 1, wherein a pseudo peptide backbone joins at least a portion of the bases of said target binding region.

30 16. The probe of claim 1, wherein said conditions include a temperature of about 60°C and a salt concentration of about 0.6 M to about 0.9 M.

17. A composition comprising said probe of claim 1 hybridized to nucleic acid derived from *Trichomonas vaginalis* under said conditions.

18. A probe mix comprising said probe of claim 1 and a helper probe.

19. The probe mix of claim 18, wherein said helper probe is up to 100 bases in length and comprises an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in a second target sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27 and SEQ ID NO:28, wherein said helper probe stably hybridizes to said second target sequence under said conditions.

20. A method for determining the presence of *Trichomonas vaginalis* in a test sample, said method comprising the steps of:

a) contacting a test sample with said probe of claim 1 under said conditions; and

b) determining whether said hybrid is present in said test sample as indication of the presence of *Trichomonas vaginalis* in said test sample.

21. A detection probe for use determining the presence of *Trichomonas vaginalis* in a test sample, said probe being up to 100 bases in length and comprising a target binding region which forms a hybrid stable for detection with a sequence contained within a target sequence selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15 and SEQ ID NO:16 under stringent hybridization conditions, wherein said probe does not form a hybrid stable for detection with nucleic acid derived from *Trichomonas tenax* under said conditions.

22. The probe of claim 21, wherein said target binding region comprises an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region of said target sequence.

23. The probe of claim 21, wherein said probe is up to 50 bases in length, and wherein said target binding region comprises an at least 15 contiguous base region which is perfectly complementary to an at least 15 contiguous base region of said target sequence.

5 24. The probe of claim 21, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of said first target sequence.

25. The probe of claim 21, wherein the base sequence of said target binding region is at least 90% complementary to the base sequence of said first target sequence.

10 26. The probe of claim 21, wherein the base sequence of said target binding region is perfectly complementary to the base sequence of said target sequence.

15 27. The probe of claim 21, wherein said target binding region comprises a base sequence which is perfectly complementary to a base sequence selected from the group consisting of SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19 and SEQ ID NO:20.

20 28. The probe of claim 21, wherein the base sequence of said probe consists of a base sequence which is at least about 80% complementary to the base sequence of said target sequence.

25 29. The probe of claim 21, wherein the base sequence of said probe consists of a base sequence which is at least about 90% complementary to the base sequence of said target sequence.

30 30. The probe of claim 21, wherein the base sequence of said probe consists of a base sequence which is perfectly complementary to the base sequence of said target sequence.

31. The probe of claim 21, wherein the base sequence of said target binding region is perfectly complementary to all or a portion of said target sequence, and wherein said

probe does not comprise any other base sequences which stably hybridize to nucleic acid derived from *Trichomonas vaginalis* under said conditions.

32. The probe of claim 31, wherein said probe is a self-hybridizing probe under said conditions and in the absence of said target sequence.

33. The probe of claim 32, wherein said probe comprises a pair of interacting labels.

34. The probe of claim 21, wherein said probe comprises a detectable label.

35. The probe of claim 21, wherein said target binding region includes at least one ribonucleotide modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety.

36. The probe of claim 21, wherein a pseudo peptide backbone joins at least a portion of the bases of said target binding region.

37. The probe of claim 21, wherein said conditions include a temperature of about 60°C and a salt concentration of about 0.6 M to about 0.9 M.

38. A composition comprising said probe of claim 21 hybridized to nucleic acid derived from *Trichomonas vaginalis* under said conditions.

39. A method for determining the presence of *Trichomonas vaginalis* in a test sample, said method comprising the steps of:

a) contacting a test sample with said probe of claim 21 under said conditions; and

b) determining whether said hybrid is present in said test sample as indication of the presence of *Trichomonas vaginalis* in said test sample.

40. An oligonucleotide for use in amplifying a target region of nucleic acid derived from *Trichomonas vaginalis*, said oligonucleotide having a target binding region up to 40 bases in length which stably hybridizes to a target sequence selected from the group consisting of SEQ ID NO:33, SEQ ID NO:34, SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39 and SEQ ID NO:40 under amplification conditions, wherein said oligonucleotide does not include any other base sequences which stably hybridize to nucleic acid derived from *Trichomonas vaginalis* under said conditions.

41. The oligonucleotide of claim 40, wherein said target sequence is selected from the group consisting of SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:43, SEQ ID NO:44, SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:47, SEQ ID NO:48, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55 and SEQ ID NO:56.

42. The oligonucleotide of claim 41, wherein said target binding region contains an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in said target sequence.

43. The oligonucleotide of claim 41, wherein said target binding region contains an at least 15 contiguous base region which is perfectly complementary to an at least 15 contiguous base region present in said target sequence.

44. The oligonucleotide of claim 41, wherein said target binding region comprises a base sequence which is perfectly complementary to said target sequence.

45. The oligonucleotide of claim 41, wherein the base sequence of said target binding region is at least about 80% complementary to said target sequence.

46. The oligonucleotide of claim 41, wherein the base sequence of said target binding region is at least about 90% complementary to said target sequence.

47. The oligonucleotide of claim 41, wherein the base sequence of said target binding region is perfectly complementary to said target sequence.

48. The oligonucleotide of claim 40, wherein said oligonucleotide includes a 5' sequence which is recognized by a RNA polymerase or which enhances initiation or elongation by RNA polymerase.

49. A method for amplifying a target region of nucleic acid derived from *Trichomonas vaginalis* present in a test sample, said method comprising the steps of:

(a) contacting said test sample with said oligonucleotide of claim 40; and
(b) exposing said test sample to said conditions for a period of time sufficient to amplify said target region.

50. The method of claim 49 further comprising providing to said test sample a capture probe under assay conditions prior to step (a), wherein said capture probe has a target binding region which stably hybridizes to said nucleic acid derived from *Trichomonas vaginalis* under said assay conditions, and wherein said capture probe has an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in a target sequence selected from the group consisting of SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31 and SEQ ID NO:32.

51. An oligonucleotide for use in amplifying a target region of nucleic acid derived from *Trichomonas vaginalis*, said oligonucleotide consisting of a target binding region up to 40 bases in length and an optional 5' sequence which is recognized by a RNA polymerase or which enhances initiation or elongation by RNA polymerase, wherein said oligonucleotide will, when contacted with a nucleic acid polymerase under amplification conditions, bind to or cause extension through a target sequence having a base sequence selected from the group consisting of: SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:43, SEQ ID NO:44, SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:47, SEQ ID NO:48, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55 and SEQ ID NO:56.

52. A method for amplifying a target region of nucleic acid derived from *Trichomonas vaginalis* present in a test sample, said method comprising the steps of:

- (a) contacting said test sample with said oligonucleotide of claim 51; and
 - (b) exposing said test sample to said conditions for a period of time
- 5 sufficient to amplify said target region.

53. A set of oligonucleotides for use in amplifying a target region of nucleic acid derived from *Trichomonas vaginalis*, said set of oligonucleotides comprising a first oligonucleotide having a target binding region up to 40 bases in length which contains an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in a first target sequence selected from the group consisting of SEQ ID NO:33, SEQ ID NO:34, SEQ ID NO:35 and SEQ ID NO:36, and a second oligonucleotide having a target binding region up to 40 bases in length which contains an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in a second target sequence selected from the group consisting of SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39 and SEQ ID NO:40, wherein said first and second oligonucleotides stably hybridize to said first and second target sequences, respectively, under amplification conditions.

54. The set of oligonucleotides of claim 53, wherein said first target sequence is selected from the group consisting of SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:43, SEQ ID NO:44, SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:47 and SEQ ID NO:48, and said second target sequence is selected from the group consisting of SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55 and SEQ ID NO:56.

55. A method for amplifying a target region of nucleic acid derived from *Trichomonas vaginalis* present in a test sample, said method comprising the steps of:

- (a) contacting said test sample with said set of oligonucleotides of claim 53; and

(b) exposing said test sample to said conditions for a period of time sufficient to amplify said target region.

5 56. An oligonucleotide for use in amplifying a target region of nucleic acid derived from *Trichomonas vaginalis*, said oligonucleotide having a target binding region up to 40 bases in length which stably hybridizes to a target sequence selected from the group consisting of SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63 and SEQ ID NO:64 under amplification conditions, wherein said oligonucleotide does not include any other base sequences which stably
10 hybridize to nucleic acid derived from *Trichomonas vaginalis* under said conditions.

15 57. The oligonucleotide of claim 56, wherein said target sequence is selected from the group consisting of SEQ ID NO:65, SEQ ID NO:66, SEQ ID NO:67, SEQ ID NO:68, SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:72, SEQ ID NO:73, SEQ ID NO:74, SEQ ID NO:75, SEQ ID NO:76, SEQ ID NO:77, SEQ ID NO:78, SEQ ID NO:79, SEQ ID NO:80, SEQ ID NO:81, SEQ ID NO:82, SEQ ID NO:83, SEQ ID NO:84, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87 and SEQ ID NO:88.

20 58. The oligonucleotide of claim 57, wherein said target binding region contains an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in said target sequence.

25 59. The oligonucleotide of claim 57, wherein said target binding region contains an at least 15 contiguous base region which is perfectly complementary to an at least 15 contiguous base region present in said target sequence.

60. The oligonucleotide of claim 57, wherein said target binding region comprises a base sequence which is perfectly complementary to said target sequence.

30 61. The oligonucleotide of claim 57, wherein the base sequence of said target binding region is at least about 80% complementary to said target sequence.

62. The oligonucleotide of claim 57, wherein the base sequence of said target binding region is at least about 90% complementary to said target sequence.

63. The oligonucleotide of claim 57, wherein the base sequence of said target binding region is perfectly complementary to said target sequence.

64. The oligonucleotide of claim 56, wherein said oligonucleotide includes a 5' sequence which is recognized by a RNA polymerase or which enhances initiation or elongation by RNA polymerase.

65. A method for amplifying a target region of nucleic acid derived from *Trichomonas vaginalis* present in a test sample, said method comprising the steps of:

- (a) contacting said test sample with said oligonucleotide of claim 56; and
- (b) exposing said test sample to said conditions for a period of time sufficient to amplify said target region.

66. An oligonucleotide for use in amplifying a target region of nucleic acid derived from *Trichomonas vaginalis*, said oligonucleotide consisting of a target binding region up to 40 bases in length and an optional 5' sequence which is recognized by a RNA polymerase or which enhances initiation or elongation by RNA polymerase, wherein said oligonucleotide will, when contacted with a nucleic acid polymerase under amplification conditions, bind to or cause extension through a target sequence having a base sequence selected from the group consisting of: SEQ ID NO:65, SEQ ID NO:66, SEQ ID NO:67, SEQ ID NO:68, SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:72, SEQ ID NO:73, SEQ ID NO:74, SEQ ID NO:75, SEQ ID NO:76, SEQ ID NO:77, SEQ ID NO:78, SEQ ID NO:79, SEQ ID NO:80, SEQ ID NO:81, SEQ ID NO:82, SEQ ID NO:83, SEQ ID NO:84, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87 and SEQ ID NO:88.

67. A method for amplifying a target region of nucleic acid derived from *Trichomonas vaginalis* present in a test sample, said method comprising the steps of:

- (a) contacting said test sample with said oligonucleotide of claim 66; and
- (b) exposing said test sample to said conditions for a period of time sufficient to amplify said target region.

5 68. A set of oligonucleotides for use in amplifying a region of nucleic acid derived from *Trichomonas vaginalis*, said set comprising a first oligonucleotide having a target binding region up to 40 bases in length which contains an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in a first target sequence selected from the group consisting of SEQ ID NO:57, SEQ ID NO:58, 10 SEQ ID NO:59 and SEQ ID NO:60, and a second oligonucleotide having a target binding region up to 40 bases in length which contains an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in a second target sequence selected from the group consisting of SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63 and SEQ ID NO:64, wherein said first and second oligonucleotides stably hybridize 15 to said first and second target sequences, respectively, under amplification conditions.

 69. The set of oligonucleotides of claim 68, wherein said first target sequence is selected from the group consisting of SEQ ID NO:65, SEQ ID NO:66, SEQ ID NO:67, SEQ ID NO:68, SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:72, 20 SEQ ID NO:73, SEQ ID NO:74, SEQ ID NO:75 and SEQ ID NO:76, and said second target sequence is selected from the group consisting of SEQ ID NO:77, SEQ ID NO:78, SEQ ID NO:79, SEQ ID NO:80, SEQ ID NO:81, SEQ ID NO:82, SEQ ID NO:83, SEQ ID NO:84, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87 and SEQ ID NO:88.

25 70. A method for amplifying a target region of nucleic acid derived from *Trichomonas vaginalis* present in a test sample, said method comprising the steps of:

- (a) contacting said test sample with said set of oligonucleotides of claim 68; and
- (b) exposing said test sample to said conditions for a period of time 30 sufficient to amplify said target region.

71. A set of oligonucleotides for use in determining the presence of *Trichomonas vaginalis* in a test sample, each of said oligonucleotides being up to 100 bases in length and having a target binding region which contains an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in a target sequence selected from the group consisting of SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92 and SEQ ID NO:93, wherein each of said oligonucleotides stably hybridizes to said target sequence under assay conditions, and wherein said target sequence is the same or different for each of said oligonucleotides.

72. The set of oligonucleotides of claim 71, wherein said set of oligonucleotides comprises a first oligonucleotide up to 100 bases in length which forms a hybrid stable for detection with said target sequence under stringent hybridization conditions, and wherein said first oligonucleotide does not form a hybrid stable for detection with nucleic acid derived from *Trichomonas tenax* under said conditions.

73. The set of oligonucleotides of claim 72, wherein said set of oligonucleotides further comprises second and third oligonucleotides, wherein said target binding region of each of said second and third oligonucleotides is up to 40 bases in length and stably hybridizes to said target sequence under amplification conditions.

74. A set of oligonucleotides for use in determining the presence of *Trichomonas vaginalis* in a test sample, each of said oligonucleotides being up to 100 bases in length and having a target binding region which contains an at least 10 contiguous base region which is perfectly complementary to an at least 10 contiguous base region present in a target sequence selected from the group consisting of SEQ ID NO:94, SEQ ID NO:95, SEQ ID NO:96 and SEQ ID NO:97, wherein each of said oligonucleotides stably hybridizes to said target sequence under assay conditions, and wherein said target sequence is the same or different for each of said oligonucleotides.

75. The set of oligonucleotides of claim 74, wherein said set of oligonucleotides comprises a first oligonucleotide up to 100 bases in length which forms a

hybrid stable for detection with said target sequence under stringent hybridization conditions, and wherein said first oligonucleotide does not form a hybrid stable for detection with nucleic acid derived from *Trichomonas tenax* under said conditions.

- 5 76. The set of oligonucleotides of claim 75, wherein said set of oligonucleotides further comprises second and third oligonucleotides, wherein said target binding region of each of said second and third oligonucleotides is up to 40 bases in length and stably hybridizes to said target sequence under amplification conditions.